The Delhi Network of Positive People

21-01-2017

To,
Mr. J.P. Nadda,
Union Minister for Health and Family Welfare,
Room No. 348, 'A' Wing,
Nirman Bhavan, New Delhi-110011

Subject: Requesting Central Government to make anti Tuberculosis drug named Delamanid available under Revised National Tuberculosis Control Program

Dear Sir,

We, the undersigned, are writing this letter to request you to make available the life-saving patented anti Tuberculosis drug - Delamanid under the Revised National Tuberculosis Control Program (RNTCP) by directing Otsuka Pharmaceuticals Co. Ltd. (Otsuka) to provide the same.

Being a group of people working with and for the well-being of people affected by Tuberculosis (TB) and particularly people living with HIV, injecting drug users, who are at a higher risk of developing TB, we are concerned about availability of Delamanid in India. The World Health Organisation (WHO) has estimated TB to be between 26 and 31 times greater in people living with HIV than among those without HIV infection.

The WHO's Global Tuberculosis Report ("the Report") suggests that by end of 2015, India had 1.7 million notified cases of TB of which 79,000 persons had Drug Resistant Tuberculosis (DR-TB). The Report also recorded a total of 5, 17, 000 TB related mortality cases in India. Of the total notified TB cases, only 26, 966 patients affected with MDR-TB and 2, 130 patients affected with XDR-TB were started on TB treatment. These numbers still don't give the complete picture as thousands of patients seeking treatment from the private sector are not reflected in this data.

Multi drug resistant TB (MDR-TB) is defined as TB that is resistant to isoniazid and rifampicin, the two most powerful TB drugs. Extensively Drug-Resistant TB (XDR-TB) is a form of TB which is resistant to at least four of the core anti-TB drugs which include – isoniazid, rifampicin, any of the fluoroquinolones (such as levofloxacin or moxifloxacin) and at least one of the three injectable second-line drugs (amikacin, capreomycin or kanamycin).

Bedaquiline and Delamanid are both recommended by WHO for use in DR-TB patients when an effective regimen cannot be designed either because of resistance (such as XDR -TB) or intolerance to another drug in the regimen. The 20th WHO Expert Committee further recommended including Bedaquiline and Delamanid in the anti - tuberculosis medicines section of the WHO Model List of Essential Medicines (EML).

India has introduced Bedaquiline in the Revised National Tuberculosis Control Program (RNTCP). However the impact of this welcome initiative is limited due to the non-availability of Delamanid.

In India, the patent for Delamanid, its intermediate, formulation and combination, is held by Otsuka. The Patents Act, 1970 requires every patentee to furnish statement regarding working the patent in India on a commercial scale by filing Form- 27. This statement gives details of the extent of commercial exploitation of the patented invention in India, by the patentee. The table below gives details of Form-27 filed by Otsuka for patents related to Delamanid.

Flat No.A 1-5, Property No. 141/3, Gali No. 3, Harijan Colony, Near IGNOU, Neb Sarai, New Delhi-110068
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Patent No.	Date of grant of patent	Status of working the patent (date of latest Form-27)	Reason given for non-working in Form-27
250365	December 29, 2011	Not worked (March 21, 2016)	Market under survey
219525	May 7, 2008	Not worked (March 24, 2015)	Not provided
248249	June 29, 2011	Not worked (March 15, 2013)	Conducting market research
244643	December 14, 2010	Not worked (March 24, 2015)	Not provided
253642	August 8, 2012	Not filed	
268015	August 12, 2015	Not worked (February 15, 2016)	Under consideration for commercialisation of patented invention

It is obvious from the above table, even after 8 years of grant of the earliest patent, Otsuka is still conducting market survey and has not worked its patent in India. While regulatory approval for Delamanid has already been granted in European Union, Japan and South Korea, no such request has been made in India. Such delay in seeking market approval is posing a hurdle to people living with MDR and XDR-TB in accessing this drug which is often viewed as salvage therapy in worst cases.

The WHO has indicated a 23% improvement in cure rates of M/XDR-TB on use of Delamanid. With present world-wide cure rate of about 28% for XDR-TB and 52% for MDR-TB, availability of Delamanid is imperative to treat the life-threatening condition. To improve outcomes for MDR/XDR-TB, at least 39 countries introduced Delamanid by the end of 2015.

We request the Central Government to direct Otsuka to provide Delamanid to facilitate its government use (particularly for RNTCP) as provided under Section 99 of Patents Act.

Calling upon Otsuka to provide Delamanid will not only ensure access to more effective medicines under RNTCP but will also help us meet the World Health Organisation's 2030 targets to reduce TB incidence and death.

We hope that the Central Government would take immediate action to ensure that Delamanid is made available to the MDR-TB and XDR-TB population.

Please contact the undersigned for any further clarifications.

Yours sincerely,

Paul Khungdim,
President
The Delhi Network of Positive People
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Signatories:
All India Drug Action Network
Access to Rights and Knowledge (ARK foundation)
Community Network for Empowerment (CoNE, Manipur)
Hepatitis Coalition of Nagaland (HepCoN)
Indian Drug Users Forum
Médecins Sans Frontières Access Campaign

Sankalp Rehabilitation Trust
Western Harm Reduction Network
Ketho Angami

Copy to

1. Ms. Nirmala Sitharaman
   Minister of State for Commerce and Industry
   Room No. 45, UdyogBhawan,
   New Delhi

2. Mr. Ramesh Abhishek,
   Secretary, Department of Industrial Policy & Promotion
   Room No. 157, Udyog Bhawan,
   New Delhi

3. Mr. C. K. Mishra,
   Secretary,
   Ministry of Health and Family Welfare,
   Nirman Bhavan, New Delhi – 110011

4. Central TB Division,
   through the Director General of Health Services,
   Ministry of Health and Family Welfare,
   Nirman Bhavan, New Delhi – 110011

5. Controller General of Patents, Designs & Trade Marks
   Boudhik Sampada Bhavan,
   Antop Hill, S.M. Road, Mumbai-400037